REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application are respectfully requested in light of the amendments above and the comments which follow.

As correctly noted in the Office Action Summary, claims 1-12, 15-16 and 41-55 were pending. By the present response, claims 1-12, 16, 41, 43, 47-50 and 56-62 have been amended. Thus, upon entry of the present response, claims 1-12, 15-16 and 41-64 remain pending and await further consideration on the merits.

Support for the foregoing amendments can be found, for example, in at least the following locations in the original disclosure: the original claims.

CLAIM REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1-12, 16, 47-50 and 56-62 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

While applicants do not concede that the identified claim language is in violation of the requirements of 35 U.S.C. §112, nevertheless in the interest of compact prosecution, applicants have proffered the foregoing amendments to claim 1 which overcomes the grounds for rejection.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 41, 43-45, 55, 63 and 64 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 7,241,316 to Evans et al. (hereafter "*Evans et*

al.") on the grounds set forth on page 3 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

The present invention is directed to compositions which are formulated such that they provide certain advantages and benefits for applications such as a moldable biocompatible implant. Compositions formed according to the principles of the present invention provide certain benefits and advantages relative to conventional biocompatible implant materials.

For example, calcium phosphate cements, which can be biodegradable, have been utilized as biocompatible implants. However, such materials often lead to the formation of dense or solid masses that inhibit osteo-conduction (see, e.g., paragraph [0006]; this is essentially the construction described by Ricci et al). Moreover, implants which are solid and contain only small pores can be disadvantageous in that the natural bone surrounding the implant cannot integrate into the implant unless the implant is degraded. Unlike an osteo-inductive and/or osteo-conductive implant, these implants have limited use for restoring the wound or defect to a more natural condition, in other words they fill rather than heal the defect (see, e.g., paragraph [0007]; this is essentially the construction disclosed by *Evans et al.*).

A composite implant mass formed according to the present invention is set forth in claim 41:

> *41. A composite implant mass comprising:*
> *a structural component, the structural component comprising a plurality of biocompatible synthetic non-polymeric granules, the granules being regularly-sized, regularly shaped, or spherical, and the granules having an equivalent diameter of about 100 μm to about 4,000 μm;*
> *a biocompatible polymer on at least a portion of each of the granules; and*

> *a plasticizer in an amount sufficient to condition at least a portion of the biocompatible polymer so that the granules of the implant mass are bound together by the biocompatible polymer, and the implant mass is plastically deformable.*

A composite matrix formed according to a further aspect of the present invention as set forth in claim 43. Claim 43 recites:

> *43. A composite matrix comprising:*
> *a structural matrix, the structural matrix comprising a plurality of biocompatible synthetic non-polymeric granules bound together, at least in part, by a biocompatible polymer coating formed on each of the granules; and*
> *an open porous region comprising macropores between adjacent coated granules;*
> *wherein the structural matrix does not contain any bone particles.*

Evans et al. is directed to devices and methods for treating defects in the tissue of a living being. However, *Evans et al.* fails to anticipate the composite matrix set forth above in claims 41 or 43.

As evident from the above, claims 41 and 43 requires non-polymeric granules bound together, at least in part, by a biocompatible synthetic polymer coating formed on at least a portion of each granule, and an open porous region comprising macropores between adjacent coated granules.

By contrast, *Evans et al.* fails to disclose this form of composite structure.

Nowhere does *Evans et al.* disclose a composite matrix which includes a plurality of biocompatible synthetic non-polymeric granules having a biocompatible synthetic polymer coating formed on (at least a portion of) each granule. Moreover, the composite disclosed by *Evans et al.* does not include an open porous region comprising macropores between adjacent coated granules.

Evans et al. fails to disclose each and every element of claim 43, much less these elements arranged as specified by claim 43.

It is noted that on page 7 of the Official Action, it is alleged that:

> It is the Examiner's position that the particles of Evans et al. are coated with polymer when the non-polymeric granules are mixed with the polymer and the plasticizer.

Since *Evans et al.* fails to explicitly disclose the above, the above-stated position is clearly one of inherency. When relying upon the theory of inherency, the Examiner must provide a basis in fact and/or a technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. See, MPEP §2112. It is respectfully submitted that the above-quoted unsubstantiated assertion is clearly inadequate to satisfy the above-stated burden. Thus, the rejection is deficient for at least this additional reason.

Thus, for at least the reasons noted above, *Evans et al.* clearly fails to anticipate the composite matrix set forth in claims 41 or 43. Claims 44, 45, 55, 63 and 64 depend from claim 43. Thus, *Evans et al.* fails to anticipate these claims for at least the same reasons noted above. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 43-45, 55, 63 and 64 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,770,695 to Ricci et al. (hereafter "*Ricci et al.*") on the grounds set forth on pages 3-4 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

The requirements of claim 43 have been noted above.

Ricci et al. discloses a time release calcium sulfate matrix for bone augmentation. However, *Ricci et al.* clearly fails to anticipate the composite matrix

set forth in claim 43 above. *Ricci et al.* discloses a composite material, as depicted in Figure 1 therein, which is reproduced below:

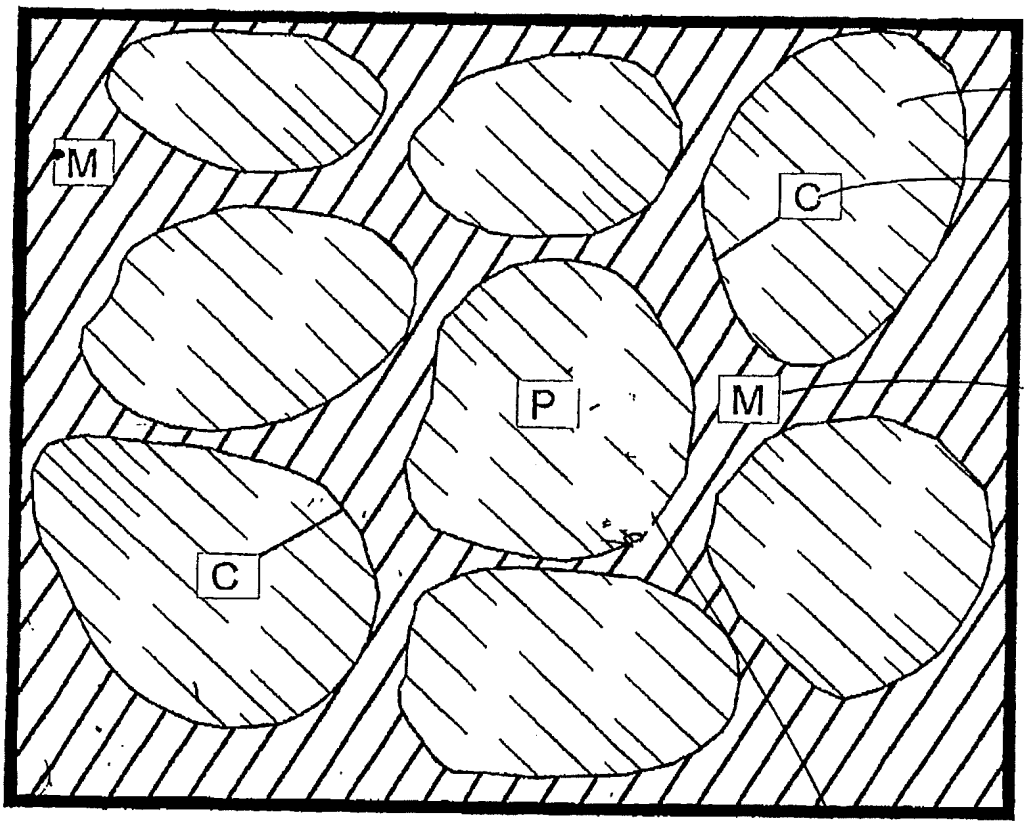

Fig. 1

As illustrated therein, the composite material includes a number of particles (P) which can comprise calcium sulfate. These particles can be provided with a polymer coating (C) a continuous matrix (M) is formed between adjacent coated particles (P), and is formed from a settable calcium sulfate compound. This composite construction is essentially in the form of a calcium sulfate cement. Such materials are discussed in paragraph [0006] of the present specification. As

disclosed therein, such materials disadvantageously lead to the formation of dense or solid formations that inhibit osteo-conduction.

As evident from the above, claim 41 requires, *inter alia*, an implant mass comprising a plasticizer in an amount sufficient that the implant mass is plastically deformable. As readily apparent from a review of the disclosure of *Ricci et al.*, the implant mass is in the form of a cement and is not plastically deformable. Moreover, claim 41 requires that the granules of the implant mass are bound together by the biocompatible polymer. By contrast, the coated particles (P) of the cement described by *Ricci et al.* are bound together entirely by the hard set calcium phosphate matrix material (M).

In addition, the composite structure of *Ricci et al.* clearly fails to include an open porous region comprising macropores between adjacent coated granules. In fact, the spaces between coated particles (P) is apparently replaced with granular tissue (G), bone growth (B), and calcium phosphate deposits (CP) upon degradation or absorption of the calcium sulfate compound matrix (M). See, e.g., Figures 2-4 of *Ricci et al.*

It is alleged on page 7 of the Official Action that the composite matrix after implantation as illustrated in Figure 3 of *Ricci et al.* satisfies the limitation of "an open porous region comprising macropores" as recited in claim 43. Applicants respectfully traverse this assertion. As clearly illustrated in Figure 3, at this stage, after implantation, the implant mass comprises bone material (see, element (B) illustrated in Figure 3 of Ricci et al.). By contrast, claim 43 expressly requires that "the structural matrix does not contain any bone particles." Therefore, the implant mass at this stage post-implantation clearly fails to satisfy the requirements of claim 43.

Thus, for at least the reasons noted above, *Ricci et al.* clearly fails to anticipate the composite matrix set forth in amended claim 43. Claims 44-45, 55, 63 and 64 depend from claim 43. Thus, these claims are also distinguishable over *Ricci et al.* for at least the same reasons noted above. Reconsideration and withdrawal of the rejection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 1-3, 5-9, 11-12, 16, 41-42, 46-54 and 56-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Ricci et al.* on the grounds set forth on pages 4-5 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

A composition formed according to the principles of the present invention is set forth in amended claim 1. Amended claim 1 recites:

> *1. A moldable implant mass composition for use in repairing a bone defect in a living organism, comprising:*
> *a plurality of biocompatible synthetic non-polymeric granules, said granules having an equivalent diameter of about 100 μm to about 4,000 μm;*
> *a biocompatible polymer coating at least a portion of the implant mass, the implant mass comprising a composite matrix of the granules bound together by the biocompatible polymer, and macropores between adjacent granules, so as to form an implant mass comprising a plurality of distinct granules coated with said biocompatible polymer, said biocompatible polymer comprising about 4% to about 20% of the total weight of the implant mass; and*
> *a plasticizer in said implant mass in an amount sufficient to condition at least a portion of said biocompatible polymer so that said implant mass is plastically deformable into a desired shape and then hardenable upon removal of at least a portion of said plasticizer from said implant mass.*

As evident from the above, claim 1 requires composition which includes a plurality of distinct granules coated with a biocompatible polymer so as to form an

implant mass. The implant mass is further defined as comprising a composite matrix of the granules bound together by the biocompatible polymer and macropores between adjacent granules. *Ricci et al.* fails to disclose at least these aspects of amended claim 1.

For reasons similar to those previously explained above, *Ricci et al.* discloses a composition in the form of a composite wherein coated granules are completely surrounded by a hard set matrix of calcium sulfate compound. See, e.g., Figure 1 of *Ricci et al.* Thus, *Ricci et al.* lacks a plurality of distinct granules coated with biocompatible polymer, and additionally lacks a configuration wherein the coated granules are bound together by the biocompatible polymer, or the presence of macropores between adjacent granules. Moreover, nowhere does *Ricci et al.* even suggest that such a construction is either desirable or possible. Thus, *Ricci et al.* fails to disclose, or even suggest, the implant composition recited in amended claim 1 for at least the reasons noted above.

A composite implant mass formed according to the principles of the present invention is set forth in amended claim 41. Amended claim 41 recites:

> *41. A composite implant mass comprising:*
> *a structural component, the structural component comprising a plurality of biocompatible synthetic non-polymeric granules, the granules being regularly-sized, regularly shaped, or spherical, and the granules having an equivalent diameter of about 100 μm to about 4,000 μm;*
> *a biocompatible polymer on at least a portion of each of the granules; and*
> *a plasticizer in an amount sufficient to condition at least a portion of the biocompatible polymer so that the granules of the implant mass are bound together by the biocompatible polymer, and the implant mass is plastically deformable.*

As evident from the above, claim 41 requires that the granules of the implant mass are bound together by the biocompatible polymer. As previously discussed,

this is not the case with the composite material of *Ricci et al.* Instead, the coated particles (P) of *Ricci et al.* are entirely bound together solely by the hard settable calcium sulfate compound matrix (M). *Ricci et al.* fails to disclose, or even suggest, that such an implant mass construction is either possible or desirable. Thus, *Ricci et al.* fails to disclose, or even suggest, the implant mass recited in amended claim 41.

Moreover, claim 41 requires that the granules have an equivalent diameter of about 100 μm to about 4000 μm. Although acknowledging that *Ricci et al.* fails to disclose this aspect of the presently claimed invention, it is nevertheless asserted that it would have been obvious to one of ordinary skill in the art to have (optimized) the particle size of *Ricci et al.* so as to lie within the claimed range. This assertion is respectfully traversed. First, it should be recognized that it is disclosed in the present specification that granules having a diameter within the claimed range are specifically selected so as to provide easy handling and processing. See, e.g., paragraph [0045] of the present specification. Moreover, such an "optimization" rationale is inappropriate where the applied prior art fails to recognize that the parameter being optimized is a result effective variable. Nowhere does *Ricci et al.* recognize that the particle size is a result effective variable. Thus, the grounds for rejection are improper for at least this additional reason.

Moreover, as evident from the above, claim 41 also requires that the composite implant mass comprises a plasticizer in an amount such that the implant mass is plastically deformable. As previously noted, the implant mass of *Ricci et al.* is not plastically deformable, it is in the form of cement. It is noted that Figure 3 of *Ricci et al.* is identified on page 7 of the Official Action as supporting the grounds for rejection. However, this is clearly not the case. In the stage depicted in Figure 3,

the implant mass is by no means plastically deformable, and likely contains no plasticizer whatsoever. Therefore, the grounds for rejection are deficient for at least this additional reason.

The remaining claims depend from either claims 1 or 41. Thus, these claims are also distinguishable over *Ricci et al.* for at least the same reasons noted above.

Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over *Ricci et al.* in view of *Evans et al.* on the grounds set forth on page 5 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Evans et al. is cited as allegedly teaching the use of biocompatible ceramics such as calcium phosphate salts. It is then asserted that it would have been obvious to substitute a calcium phosphate salt for the calcium sulfate material disclosed by *Ricci et al.* This assertion is respectfully traversed. *Ricci et al.* is specifically targeted to solving the bio-absorption rate problem associated with calcium sulfate materials. In fact, *Ricci et al.* acknowledges the use of calcium phosphate ceramics in bone augmentation materials in the prior art, but specifically addresses calcium sulfate, which has different absorptive properties than calcium phosphate. Therefore, one of ordinary skill in the art would not have simply substituted calcium phosphate for calcium sulfate in the material disclosed by *Ricci et al.*

Moreover, even if the alleged teachings of *Evans et al.* were applied to *Ricci et al.* exactly as suggested in the grounds for rejection, the claimed invention would not result. Namely, the alleged teachings of *Evans et al.* fails to cure the deficiencies previously noted above in connection with the requirements of amended claim 1.

Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 10 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Ricci et al.* in view of U.S. Patent No. 7,001,551 to Meredith (hereafter "*Meredith*") on the grounds set forth on page 5 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Meredith is cited as allegedly teaching inclusion of a growth factor in an implantable composition. However, even if the alleged teachings of *Meredith* were applied to *Ricci et al.* exactly as suggested in the grounds for rejection, the claimed invention would not result. Namely, the alleged teachings of *Meredith* fail to cure the deficiency of *Ricci et al.* with respect to the requirements of amended claim 1. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 15 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Ricci et al.* in view of U.S. 4,430,760 to Smestad (hereafter "*Smestad*") on the grounds set forth on page 5 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Smestad is cited on page 6 of the Official Action as allegedly teaching the inclusion of a porous casing or membrane to contain a filling material used to repair a bone defect. While not agreeing to the interpretation of *Smestad* given on the grounds for rejection, even if the alleged teachings of *Smestad* were to be applied to *Ricci et al.* exactly as suggested in the grounds for rejection, the claimed invention would not result. Namely, the alleged teachings of *Smestad* fail to cure the deficiencies of *Ricci et al.* previously noted above in connection with the requirements of amended claim 1. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 42 and 46 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Evans et al.* on the grounds set forth on page 6 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Claim 46 depends from claim 43, and claim 42 depends from claim 41. The deficiencies of *Evans et al.* with respect to the requirements of amended claims 41 and 43 have been discussed above.

It is acknowledged that *Evans et al.* fails to disclose the claimed weight percentage of bio-compatible polymer in the composite matrix. Nevertheless, it is alleged that it would have been obvious to one of ordinary skill in the art to have provided the bio-compatible polymer and the claimed weight percentage through routine optimization. This assertion is respectfully traversed. Such "optimization" rationales are inappropriate when the prior art fails to recognize that the parameter being optimized is a result-effective variable. *Evans et al.* fails to recognize that the amount of polymer present in the composite material is a result effective variable. Thus, the rationale set forth in the grounds for rejection is improper. Reconsideration and withdrawal of the rejection is respectfully requested.

Regardless of whether the amount of bio-compatible polymer recited in claim 42 or 46 would have been obvious in view of *Evans et al.*, *Evans et al.* still fails to disclose, or even suggest, the composite matrix material defined by amended claim

41 or 43 for at least the reasons noted above. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Respectfully submitted,

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